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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/534,092	03/23/2000	Waleed H. Hassanein	2601.1001-009	9125

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EXAMINER

SAUCIER, SANDRA E

ART UNIT PAPER NUMBER

1651

10

DATE MAILED: 08/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/534,092

Applicant(s)
Hassanein

Examiner
Sandra Saucier

Art Unit
1651



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jun 6, 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 and 23-34 is/are pending in the application.
- 4a) Of the above, claim(s) 1-16 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 23-34 is/are allowed.
- 6) ☒ Claim(s) 17, 18, and 21 is/are rejected.
- 7) ☒ Claim(s) 19 and 20 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other: _____

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DETAILED ACTION

Claims 1-21, 23-34 are pending. Claims 17-21, 23-34 are considered on the merits. Claims 1-16 are withdrawn from consideration as being drawn to a non-elected invention.

Election/Restriction

Please cancel claims 1-16 in the next response in order to facilitate prosecution.

Claim Rejections – 35 USC § 102

Claims 17, 18, 21 remain rejected under 35 U.S.C. 102(b) as being clearly anticipated by Turpin *et al.* [V] in light of Dobrian *et al.* [W] or Birkett *et al.* [X] or Watanabe *et al.* [Z].

The claims are directed to a composition comprising:

- (1) a metabolizable carbohydrate (glucose),
 - (2) sodium chloride,
 - (3) potassium (ion),
 - (4) calcium (ion),
 - (5) magnesium (ion),
 - (6) bicarbonate ion,
 - (7) epinephrin(e)
 - (8) adenosine
- free of non-metabolizable impermeants
pH about 7.4-8.5

The references are relied upon as explained below.

Turpin *et al.* discloses a composition comprising Krebs-Ringer bicarbonate buffer with 1.5% albumin at pH 7.4 (page 443, methods) to which has been added 0.3µM epinephrine plus adenosine 0.1µM (legend Fig. 4). Albumin is a cytoprotective agent as demonstrated by its antioxidative properties (Dobrian *et al.*) and is well know to have fatty acids and steroids associated with it (Birkett *et al.* and Watanabe *et al.*).

Thus, the composition of Turpin *et al.* which comprises albumin would also contain antioxidant, steroid and fatty acid by virtue of the fact that albumin preparations contain steroid and fatty acid and exhibit antioxidative properties.

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Response to Arguments

Applicant's arguments filed 6/6/03 have been fully considered but they are not persuasive.

The examiner apologizes for using the phrase "in view of" which is a phrase associated with obviousness rejections instead of the phrase "in light of" which is used to indicate that the primary reference has all of the claimed elements as explained with the assistance of the secondary references.

Applicant points out that the BSA used in the composition of Turpin *et al.* is fatty acid poor. However, fatty acid poor is not the same as fatty acid free and it is noted that no concentration limitations are present in the claims. Thus, one molecule of a fatty acid would fulfill the claim limitations. Applicant further argues that Turpin *et al.* disclose that free fatty acids do not accumulate in the perfusion system. While this may be true, please note that the claims do not require that the fatty acids be free in the media. Further, while the fatty acids may not accumulate in the media, it is reasonable to assume that at least some molecules of fatty acid bound to BSA are in equilibrium with at least some free fatty acid in the media since the fatty acids are not covalently bound.

Allowable Subject Matter

Claims 19 and 20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 23-34 are allowable.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

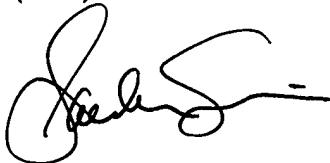
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1651. The supervisor for 1651 is M. Wityshyn, (703) 308-4743. The normal work schedule for Examiner Saucier is 8:30AM to 5:00 PM Monday, Tuesday and 8:30 to noon on Wednesday.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (703) 308-1084. Status inquiries must be directed to the Customer Service Desk at (703) 308-0197 or (703)-308-0198. The number of the Fax Center for the faxing of official papers is (703) 872-9306 or for after finals (703) 872-9307.

A handwritten signature in black ink, appearing to read 'Sandra Saucier', with a stylized flourish at the end.

Sandra Saucier
Primary Examiner
Art Unit 1651
July 30, 2003